

*REMARKS/ARGUMENTS**Present Invention and Pending Claims*

Claims 2-4 and 6-8 are currently pending and are directed to a method of treating a condition of schizophrenia (claims 2-4), wherein the condition of schizophrenia is a negative symptom or cognitive disorder (claims 6-8).

Amendments to the Claims

The claims have been amended to more particularly point out and distinctly claim the present invention. Claim 1 has been canceled. As such, claim 2 has been amended so as to place it in independent form. Claim 2 also has been amended to narrow the scope of compounds encompassed by formula (Ia) and to correct an inadvertent typographical error (i.e., “and” has been replaced with “or”). Claim 5 has been canceled as being dependent upon canceled claim 1.

In addition, the claims have been amended to place them in a format more consistent with U.S. patent practice. Specifically, the originally filed intended use claim language of “a therapeutic agent for schizophrenia” has been deleted, and the claims now recite a method of treating a condition of schizophrenia by administering a compound of the formula (Ia). Support for this amendment can be found in the present specification at, for example, page 1, lines 18-22; page 10, lines 18-32; page 12, line 25, through page 13, line 2; page 14, lines 15-21; and the originally filed claims.

No new matter has been added by way of these amendments.

Summary of the Office Action

The Examiner has set forth in writing the telephonic species restriction requirement issued on January 24, 2007. The Examiner has requested that Applicants affirm the provisional species election, with traverse, of 2-(2-oxopyrrolidin-1-yl)-N-(2,3-dimethyl-5,6,7,8-tetrahydrofuro[2,3-b]quinolin-4-yl)acetamide. The Examiner has indicated that if the claims as limited to the selected species are found allowable, then the Examiner will expand the prior art search to include other species that are encompassed by the pending claims.

The Examiner has rejected claims 1-8 under 35 U.S.C § 102(b) as allegedly anticipated by the Gualtieri reference (*Pharmaceutica Acta Helvetiae*, 74: 85-89 (2000)). Additionally, claims 1-8 have been rejected under 35 U.S.C § 112, first paragraph, as allegedly lacking enablement.

Reconsideration of the pending claims is respectfully requested.

Discussion of the Restriction Requirement

Applicants hereby affirm the provisional species election, with traverse, of 2-(2-oxopyrrolidin-1-yl)-N-(2,3-dimethyl-5,6,7,8-tetrahydrofuro[2,3-b]quinolin-4-yl)acetamide, as encompassed by pending claims 2-4 and 6-8.

The Examiner asserts that the pending claims contain a compound formula which is generic to a plurality of patentably distinct species. In particular, the Examiner alleges that the species encompassed by the pending claims are distinct in that the species have different chemical structures and pharmacological mechanisms of action. The Examiner also alleges that a search directed to the generic formula of the pending claims would represent an undue burden because the species can be grouped into differing classifications.

There are two criteria for a proper requirement for restriction (including an election of species) between patentably distinct inventions (or species): (i) the inventions must be independent or distinct as claimed, and (ii) there must be a serious burden on the Examiner if restriction is not required. M.P.E.P. § 803. Consequently, as set forth in M.P.E.P. § 803: "If the search and examination of all the claims in an entire application can be made without serious burden, the examiner must examine them on the merits, even though they include claims to distinct or independent inventions."

Moreover, as is also stated in M.P.E.P. § 803, mere assertions as to the requirements for restriction are insufficient; rather, "Examiners must provide reasons and/or examples to support conclusions." As discussed at M.P.E.P. § 806.05(h), a mere allegation, without support, is insufficient to support a restriction requirement. Rather, "[t]he burden is on the examiner to provide an example ... [and] the burden is on the examiner to support a viable alternative use or withdraw the requirement." See also Examiner Notes 2(a) and 2(b) at M.P.E.P. § 806.05(h).

In addition, even if related species are shown to be distinct under the criteria of M.P.E.P. § 806.05 (c)-(i), “the examiner, in order to establish reasons for insisting upon restriction, must explain why there would be a serious burden on the examiner if restriction is not required ... [and] must show by appropriate explanation one of the following: (1) separate classification thereof ... (2) a separate status in the art when they are classifiable together ... (3) a different field of search.” M.P.E.P. § 808.02.

In the present case, the Examiner merely has asserted that the compounds encompassed by the pending claims belong to separate classes and has not provided any specific examples thereof. Thus, the Office has failed to show by appropriate explanation any separate classification, separate status in the art when classifiable together, or a different field of search for the claimed subject matter. “Where ... the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing among independent or related inventions.” M.P.E.P. § 808.02.

Accordingly, Applicants respectfully submit that the election of species requirement is improper and request that it be withdrawn.

Discussion of the Anticipation Rejection

According to the Examiner, the Gualtieri reference teaches each of the elements of the present invention as defined by the pending claims. More specifically, the Examiner contends that the Gualtieri reference teaches 2-(2-oxopyrrolidin-1-yl)-N-(2,3-dimethyl-5,6,7,8-tetrahydrofuro[2,3-b]quinolin-4-yl)acetamide (referred to therein as MKC-231).

However, the Gualtieri reference does not disclose or suggest that the recited compound is useful in the treatment of schizophrenia. Since the Gualtieri reference does not teach or suggest the treatment of schizophrenia with the compound in question, the Gualtieri reference does not anticipate the present invention as defined by the pending claims.

Moreover, the Gualtieri reference does not render the present invention obvious. The Gualtieri reference only discloses that 2-(2-oxopyrrolidin-1-yl)-N-(2,3-dimethyl-5,6,7,8-tetrahydrofuro[2,3-b]quinolin-4-yl)acetamide is a high affinity choline uptake (HACU) enhancer. In addition, the Gualtieri reference is directed to the treatment of Alzheimer's

disease. As such, the treatment of schizophrenia is not discussed therein. Thus, the Gualtieri reference does not teach or suggest the benefits that a compound such as 2-(2-oxopyrrolidin-1-yl)-N-(2,3-dimethyl-5,6,7,8-tetrahydrofuro[2,3-b]quinolin-4-yl)acetamide has with respect to the treatment of schizophrenia. Without such a teaching or suggestion, one of ordinary skill in the art would not be motivated to modify the teachings of the Gualtieri reference in order to arrive at the present invention, e.g., to use the disclosed compounds to treat schizophrenia.

In view of this lack of motivation to modify the teachings of the Gualtieri reference, as well as the failure of the Gualtieri reference to disclose or suggest each element of the pending claims, the present invention as defined by the pending claims must be considered novel and unobvious in view of the Gualtieri reference. Accordingly, the anticipation rejection based on the Gualtieri reference should be withdrawn, and, moreover, an obviousness rejection of the pending claims would not be proper.

Discussion of the Enablement Rejection

According to the Examiner, the specification, while being enabled for treating schizophrenia with the elected species, does not enable the treatment of schizophrenia with all of the possible compounds encompassed by formula (I). The Examiner points out that Applicants only provide working examples for treating schizophrenia with the elected species, not any other compounds. As such, the specification allegedly fails to provide information that would allow one of skill in the art to practice the present invention without undue experimentation. This rejection is traversed for the reasons set forth below.

Contrary to the Examiner's allegation, the present application reasonably provides enablement for treating schizophrenia with all of the compounds encompassed by the amended claims. More specifically, the specification clearly teaches that 4-acylamino-tetrahydrofuro[2,3-b]quinoline derivatives of formula (Ia), as encompassed by the amended claims, are effective in phencyclidine (PCP)-induced passive avoidance reaction tests (i.e., rat models for the conditions of schizophrenia) (see, for example, the specification at page 10, lines 28-32).

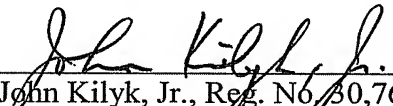
In addition, Applicants need not exemplify each and every embodiment of the claimed invention. Applicants need only teach those of ordinary skill in the art how to make

and use the present invention. In this regard, Applicants point out that Example I of the instant specification describes the effectiveness of 2-(2-oxopyrrolidin-1-yl)-N-(2,3-dimethyl-5,6,7,8-tetrahydrofuro[2,3-b]quinolin-4-yl)acetamide for the treatment of conditions of schizophrenia, as modeled by the phencyclidine (PCP)-induced passive avoidance reaction test. As discussed above, other exemplary 4-acylamino-tetrahydrofuro[2,3-b]quinoline derivatives that are useful for the treatment of conditions of schizophrenia and encompassed within the amended claims of the present application (i.e., those compounds of formula (Ia)) are described in the specification at, for example, page 10, lines 28-32. Chemical synthesis of such quinoline compounds and suitable dosages are additionally described in the specification (see, for example, page 10, lines 11-17, and page 10, line 33, through page 11, line 9, respectively). Further, suitable formulations and modes of administration are also described in the specification (see, for example, page 11, line 10, through page 12, line 24). Therefore, no undue experimentation would be required for one of ordinary skill in the art to practice the method of the present invention. Accordingly, the subject matter of claims 2-4 and 6-8 is enabled by the specification, and the enablement rejection should be withdrawn.

Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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